

PATENT COOPERATION TREATY

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REC'D 11 FEB 2005

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

07 APR 2005

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P 03-472 AE/KES		FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE 2003/001574	International filing date (day/month/year) 09.10.2003	Priority date (day/month/year) 10.10.2002	
International Patent Classification (IPC) or national classification and IPC A61M 39/10, G06K 7/10			
Applicant MEDICAL VISION RESEARCH & DEVELOPMENT AB et al			

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 10.05.2004	Date of completion of this report 20.01.2005
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/001574

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1 - 7 _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* 9 - 10 _____ received by this Authority on 01.11.2004

pages* _____ received by this Authority on _____

☒ the drawings:

pages 1 - 2 _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/001574

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-7</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-7</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-7</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)

This report is based on new claims filed after the Written Opinion.

The claimed invention

The claimed invention relates to the problem concerning preventing that an improper sterile product is connected to medical technical equipment.

The problem is solved by arranging a fixed identification tag on the sterile product. The tag is read by a sensor on the equipment without touching the sterile product and a decision is made whether the sterile product is suitable to use or not.

Prior art

In the International Search Report the following documents were cited:

D1: DE19822751
D2: US5591344
D3: WO0174421
D4: WO9305829
D5: US5131823
D6: EP1101506
D7: US5078683

D3 describes an angiographic injector subassembly. In D3 a bar code is placed on a sterile syringe and is read by a reader on the syringe holder. The bar code information is processed and the system is blocked and information is presented to the user if not an appropriate bar code was read. This system prevents the use of incompatible syringes. (See page 14, line 20-28.)

D5 describes a device for joining a connection piece to a peristaltic pump. (See figure 1-3 and abstract.)

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V.

D6 describes a medical gas delivering system. In D6 a sterile filter is attached to the gas delivering equipment. The sterile filter comprises a machine readable identification element, for example a bar code. When the filter is connected to the equipment the bar code is placed in front of reading unit that identifies the filter. Based in this identification an evaluation process starts. An evaluation unit comprises a memory, in which information on filters is stored. If a filter has been used before the memory contains information about this and the system then blocks the gas supply and alerts the user. If the filter has not been used before the system will start delivering gas. (See paragraphs 0008-0009 and 0016.)

Documents D1, D2, D4 and D7 represent the prior art. The claimed invention is not considered to be anticipated by these documents.

Statement of reason

The cited documents represent the general state of the art.

The invention defined in claims 1-7 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed identification device. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-7 is novel and is considered to involve an inventive step. The invention is industrially applicable.

PCT/SE03/01574 - AMENDED CLAIMS FILED 1 Nov. 2004

1. A medical-technical identification device for identifying a sterile product (4, 62, 72, 82), for example a product intended for one-time-use only, when connected to a piece of medical equipment (1, 60, 70, 80), and in that the sterile
5 product (4, 62, 72, 82) includes a fixedly mounted information carrier (9, 63, 73, 83) which is adapted to deliver or to offer specific product information in a contactless fashion to a reading element (12, 64, 74, 84) connected to the equipment (1, 60, 70, 80), and that the reading element (12) is connected to a registering unit (13) which, in turn, is connected to both a storage unit (14) and an
10 analysing unit (15), **characterised** in that the product is a sterile elastic hose part (4) or a sterile saw blade (62) or a sterile drill bit (72) or a sterile shaver blade (82) and that the analysing unit (15) functions to deliver signals to an equipment-actuating control unit and in that the device includes a presentation unit (16) which functions to present information from both the analysing unit (15) and the storage
15 unit (14) and in that a programming unit is connected to one of said units.

2. An identification device according to claim 1, **characterised** in that the information carrier (9) is mounted in or on one side of a holder (8) and in that the reading element (12) is mounted in or on one side of a fixation seat (7), wherein
20 the exchange of information between the information carrier (9) and the reading element (12) does not take place until the holder is in place in the seat (7), i.e. until connection of the hose part (4) to the equipment has been completed.

3. An identification device according to claim 2, **characterised** in that the
25 information carrier (9) and the reading element (12) are adapted to take fixed positions relative to one another when the hose part (4) is connected actively to said equipment.

4. An identification device according to claim 3, **characterised** in that the
30 holder (8) of the information carrier (9) includes a planar slide surface (10) which is angled such that the normal to said surface will not extend parallel with the symmetry axis of said hose part (4) and in that said slide surface conforms to or fits with a correspondingly directed slide surface (11) in the seat (7).

5. An identification device according to claim 4, **characterised** in that both slide surfaces (10, 11) are directed so that an applied force intended to press the surfaces (10, 11) together will cause the information carrier (9) and the reading element (12) to be aligned mutually in the direction of an X-axis and Y-axis.

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6. An identification device according to claim 5, **characterised** in that both slide surfaces (10, 11) are directed so that the information carrier (9) and the reading element (12) will also be mutually aligned in the direction of an Z-axis.

10 7. An identification device according to any one of claims 1 - 6, **characterised** in that the transmission of information between the information carrier (9) and the reading element (12) is caused to take place with the aid of one or more of the following devices: bar codes, Blue Tooth, radio waves, light waves, e.g. infrared light, electromagnetism, radioactivity or chemical transmission.

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